

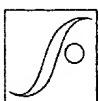
PHARMACEUTICALLY ACTIVE HERBAL PREPARATION FOR THE TREATMENT
OF MIGRAINE

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The invention pertains to a pharmaceutically active herbal preparation with improved effectiveness for the all-encompassing treatment of migraine, the preparation containing plant components and/or preparations of *Tanacetum parthenium* in combination with *Vitex agnus-castus* and/or *Cimicifuga racemosa* and/or *Zingiber officinale* as pharmaceutically active components.

Migraine is understood today as a complex functional disturbance of neuronal and vascular elements of the CNS. The headaches associated with it are apparently induced by an aseptic inflammation of the blood vessels and the dura mater vessels of the brain in association with permeability of the vessel walls for albumin and the release of neurotransmitters such as serotonin and tryptamine. The disorder is characterized by the following sequence of events: vasodilation, activation of the trigeminus, and neurogenic inflammation. Migraine attacks occur abruptly and repeatedly. They involve headaches on one side of the head, which can be associated with various accompanying phenomena: autonomic symptoms such as nausea and vomiting, aversion to light and noise, visual symptoms such as disturbed vision, and also neurological breakdowns such as paralysis or disturbances in language or speech. The symptoms, nausea and vomiting, are caused by the absence of gastrointestinal peristalsis. Most (70%) migraine patients are women. They are more likely to suffer migraine during their menstrual periods. The treatment of migraine has been limited so far to the treatment of the headaches as a way of relieving the patient's discomfort. A more effective and improved treatment of migraine by means of phytopharmaceutical preparations to address the other symptoms of migraine is not known.

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[illegible]

The task of the present invention is to provide a more effective phyto-pharmaceutical drug with improved efficacy for the treatment of migraine and with few if any side effects.



The surprising discovery has now been made that the task according to the invention can be accomplished by a combination of *Tanacetum parthenium* with other medicinal plants such as *Vitex agnus-castus* and/or *Cimicifuga racemosa* and/or *Zingiber officinale* (ginger). The combination of *Tanacetum parthenium* with *Zingiber officinale* leads to a significant improvement in efficacy; in addition to the alleviation of the headache, the other symptoms of migraine, including especially vertigo, nausea, and gastrointestinal complaints can also be minimized. The combination of *Tanacetum parthenium* with *Vitex agnus-castus* or *Cimicifuga racemosa* as well as the three-fold combination of *Tanacetum parthenium*, *Zingiber officinale*, and *Vitex agnus-castus* lead to a considerable enhancement of the effect or alleviation of all the symptoms of migraine, especially in women whose migraine attacks are concentrated in the time around their periods.

Vitex agnus-castus (monk's pepper, chaste tree) belongs to the Verbenaceae family (vervain, verbena). The fruits are the part of the plant which is used. Various secondary plant compounds have been detected as constituents such as iridoids, flavonoids, and ethereal oils. The ability of these compounds to direct their attack against lactotropic cells and to bind themselves to the dopamine receptors there explains why they are so effective in relieving premenstrual syndrome. The term "premenstrual syndrome" is understood to mean a recurring set of psychological and physical disturbances and/or changes in behavior, which normally can occur only in the corpus luteum phase of the menstrual cycle. The increase in prolactin secretion associated with this disorder is significantly reduced by the phytopharmaceutical of the invention. An excessive level of prolactin in the blood lowers pulsatile [? -- Tr. Ed.] gonadotropin secretion, which is ultimately the key factor in determining



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Zingiber officinale (ginger) is important throughout the world as a spice and as basic material in the food industry, but has also been used medicinally for centuries. It is the root of the *Zingiber officinale* plant which is used pharmaceutically; it contains up to 3% of ethereal oil (ginger oil), the chief components of which quantitatively are sesquiterpene hydrocarbons and sesquiterpene alcohols, primarily zingiberene (30%) and β -bisabolene (10-15%). In addition, it also contains various acrid compounds such as gingerols and shogaols, which are highly effective therapeutically. *Zingiber officinale* is used in modern Western medicine chiefly in the form of powders, extracts, distillates, infusions, tinctures, and the ethereal *Zingiber officinale* oil. It is used to prevent the symptoms of travel sickness, but also quite generally as an antiemetic. In addition, *Zingiber officinale* is used as a carminative, a spasmolytic, an antifatulent, a digestive, an aperitive, a stomachic, an expectorant, and antitussive, an astringent, a stimulant, and a tonic.

The herbal preparations can be in the form of extracts, powders, distillates, infusions, tinctures, and oils.

The herbal preparation according to the invention can be in the form of capsules, film-coated tablets, solutions, sugar-coated tablets, suppositories, effervescent tablets, chewable tablets, or effervescent granulate.

The amount of the plant components used in the herbal preparation according to the invention, i.e., the amount of the preparation of *Tanacetum parthenium*, is selected so that it corresponds to 0.1-1 mg, and especially 0.2-0.6 mg, of parthenolide.

The amount of plant components or of the preparation of *Cimicifuga* used in the herbal preparation according to the invention is 20-100 mg.

The amount of plant components or of a preparation of *Vitex agnus-castus* used in the herbal preparation according to the invention is 20-100 mg, where preferably an amount of 20-40 mg is used.

The amount of plant components or of a preparation of *Zingiber officinale* used in the herbal preparation according to the invention is 0.5-6 g, where preferably an amount of 1-4 g is used.

The use of the herbal preparation according to the invention, which contains plant components and/or preparations of *Tanacetum parthenium* in combination with additional plant components selected from the group consisting of *Vitex agnus-castus* and/or *Cimicifuga racemosa* and/or *Zingiber officinale*, is intended for the treatment or prevention of migraine, especially in women in association with their periods, or of menstrual complaints or of additional gastrointestinal complaints.

Tanacetum parthenium combined with *Vitex agnus-castus*, *Tanacetum parthenium* combined with *Cimicifuga racemosa*, *Tanacetum parthenium* combined with



Zingiber officinale, and *Tanacetum parthenium* combined with *Vitex agnus-castus* and *Zingiber officinale* represent the preferred combination preparations according to the invention with respect to the use described above.

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